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No. 87-498

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR PETITIONERS

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QUESTIONS PRESENTED

I. Whether employees of the regulating agency under section 262(d) of the Public Health Service Act have discretionary authority to license a live-virus vaccine that does not comply with the agency's safety regulations.

II. Whether the United States is immune from tort liability under section 2680(a) of the Federal Tort Claims Act when its employees act in violation of statutory and regulatory directives that do not provide for the exercise of policy judgment.

LIST OF PARTIES

The petitioners are Kevan Berkovitz, a minor, by his parents and natural guardians Arthur Berkovitz, his wife, Donna Berkovitz, and Arthur Berkovitz and Donna Berkovitz, in their own right.

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BRIEF FOR PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. pp. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-40a) has not been reported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. Berkovitz' petition for rehearing or rehearing en banc was denied on July 22, 1987, with three judges indicating they would grant rehearing en banc. The petition for writ of certiorari was filed on September 25, 1987, and was granted on January 11, 1988. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

This case presents the question whether the United States is immune from tort liability under section 2680(a) of the Federal Tort Claims Act when its employees act in violation of statutory and regulatory directives that do not provide for the exercise of policy judgment.

The following points are not at issue here. First, there is no issue as to whether Petitioners have made out a *prima facie* case under sections 1346(b) and 2674 of the FTCA, providing that the government shall be liable in tort in the same manner and extent as a private individual, as determined by the law of the place where the act or omission occurred.[1]

Second, the validity of the agency's regulations is not questioned by Petitioners in this action. To the contrary, the only challenge to the authority of these regulations came from the agency employees who disregarded them, and from the agency representatives who now claim discretion to violate them.

Finally, there is no issue presented regarding the adequacy of proof to sustain the allegations. It is admitted for present purposes that the conduct in question violated agency regulations.[2]

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[1] Whether Petitioners' claim was actionable under state law was raised in the government's brief to the district court. Petitioners were granted leave to amend the complaint to aver specifically that the government's conduct increased the risk of harm to Kevan Berkovitz. The complaint, so amended, was found to state a cause of action under Pennsylvania law. The government did not include this issue in its request for certification for interlocutory appeal, and it was not considered or ruled on by the court of appeals.

[2] Since the issue was joined in the context of a Rule 12(b) motion to dismiss, the allegations of Petitioners' complaint must be accepted as true. The action may be dismissed only if it appears beyond doubt that Petitioners can prove no set of facts in support of the claim which would entitle them to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

The facts of the case are as follows. On May 10, 1979, Kevan Berkovitz received a dose of live poliovirus vaccine from his pediatrician in Charleroi, Pennsylvania. One month later he contracted paralytic poliomyelitis. He was not yet three months old. The Communicable Disease Center determined that Kevan's polio was caused by the vaccine. (J.A. 9, ¶ 5)

In 1944 Congress passed the Public Health Service Act, 42 U.S.C. § 201, *et seq.* directing that biologic products, including live poliovirus vaccines, could not be produced or distributed by private manufacturers without a federal license. 42 U.S.C. § 262(a). The enabling provisions for federal regulation of biologic products are contained in Subchapter II, "General Powers and Duties". In section 262(d) Congress granted authority to the Department of Health and Human Services, through its Division of Biologic Standards (DBS), to issue a license:

> . . . only upon a showing that the establishment and products for which a license is desired meet standards, designed to insure the continued safety, purity and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. Licenses shall be issued, suspended, and revoked as prescribed by regulations.

42 U.S.C. § 262(d) (S.A. 3).[3] Regulations promulgated by the Surgeon General to implement the statute reiterated that, "A product license shall be issued only upon examination of the product and upon a determination

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[3] Section 262(d) was unaffected by the 1986 amendments to the Act, Pub. L. No. 99-660, § 105(a), § 315, 100 Stat. 3751, 3783 (1986).

that the product complies with the standards prescribed in the regulations." [4]

In the early 1960's DBS received a license application for an attenuated live poliovirus strain. This virus strain was the genetic parent of the vaccine which paralyzed Kevan. Regulatory criteria for original virus strains require the application to demonstrate that the virus was tested on a specified human population without harmful effect.[5] Further, it must be demonstrated that the virus was subjected to replication in the manner prescribed in the regulations—the manufacturing process being essentially a process of limited and controlled replication—and produced a consumer level vaccine that met all safety requirements.[6]

The application submitted to DBS demonstrated that the virus strain for which a license was sought *caused* paralysis in the human test population and was not, therefore, "without harmful effect." (J.A. 11, ¶ 17(c)). The data further demonstrated that the consumer level vaccine produced from the strain failed to meet the neurovirulence criteria of the regulations.[7] (J.A. 12, ¶ 17(g)).

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[4] 42 C.F.R. § 73.5(a) (S.A. 4). Under 42 C.F.R. § 73.3 (S.A. 4), the licensing application "shall not be considered as filed" if all required test data is not submitted.

[5] 42 C.F.R. § 73.110(b)(2) (S.A. 6).

[6] *Id.* It should be noted that there are three types of poliovirus, referred to as Types 1, 2 and 3. An original virus strain is separately licensed for each type. A type 1 strain is used to produce Type 1 seed viruses, which produce Type 1 monovalent vaccine pools (monopools). At the end of the manufacturing process, monopools of each of the three types are combined to form a trivalent vaccine. At issue here is the Type 3 strain, and a production seed and monopool derived therefrom.

[7] Neurovirulence is the capacity of an infectious agent to produce pathologic effects on the central nervous system. *Dorland's Medical Dictionary*, 26th Ed., 1985, p. 891. In this context it refers to the vaccine's ability to cause paralytic poliomyelitis. The neurovirulence

Although the strain violated the conditions for licensing prescribed in the regulations, an employee of the agency issued a product license permitting the virus to be used in vaccine manufacture.

After this license was issued, DBS received a product license application for a Type 3 [8] production seed virus grown from the original strain and designated "45-B-85". Seed viruses are the intermediate step in the manufacturing process—the first progeny of the original virus and the progenitor of vaccine monopools. Each production seed must be individually licensed; regulations require the application to demonstrate that the seed virus was tested for neurovirulence by intrathalamic, intraspinal and intramuscular injection in Macaca monkeys.[9] Neurovirulence is determined according to prescribed criteria, including: the number of monkeys showing lesions; the severity of the lesion; the dissemination of the lesion (distance from the inoculation site); and the rate of occurrence of paralysis.[10] The criteria are met:

> only if at least 80 percent of the animals survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the reference.[11]

The data submitted with the application for 45-B-85 did *not* demonstrate that the seed had been subjected to the neurovirulence testing required by the regulations. In fact, the tests were not performed. The agency employee

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criteria, discussed *infra* in greater detail, are the most critical in evaluating vaccine safety.

[8] *See* n.6, *supra*.

[9] 42 C.F.R. § 73.110(b)(4) (S.A. 6).

[10] 42 C.F.R. § 73.114(b)(1)(iii) (S.A. 8).

[11] *Id.*

who reviewed the application nevertheless issued a product license for 45-B-85. (J.A. 12).

The production seed is used to manufacture vaccine monopools, which are combined to form the consumer level product. Data submitted to the agency [12] demonstrated that 45-B-85, after licensing, was producing vaccine monopools which exceeded the neurovirulence criteria of the regulations, indicating a deterioration of the seed's neurovirulence properties and genetic instability. (J.A. 12). The regulations provide that whenever there is evidence of a change in the neurovirulence of a production virus, it must be requalified in accordance with the original licensing criteria.[13] The regulations further provide that the Surgeon General shall recommend that a product license be suspended or revoked when the product fails to conform to regulatory standards.[14] The license may subsequently be reinstated only upon a showing of compliance with the original licensing criteria. Although 45-B-85 demonstrated non-compliance, no action was taken to revoke its license. (J.A. 12). It continued in use and subsequently produced the Type 3 monopool which caused Kevan's paralysis.

The vaccine monopools produced from the seed virus do not require product licenses. However, prior to distribution of a vaccine lot the manufacturer must test the vaccine for neurovirulence according to the prescribed criteria.[15] The regulations provide that no lot of vaccine

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[12] Under 42 C.F.R. § 73.116(g), the manufacturer must submit such test data to the agency.

[13] 42 C.F.R. § 73.110(b)(5) (S.A. 7).

[14] 42 C.F.R. § 73.9 (S.A. 5).

[15] 21 C.F.R. § 610.1 (S.A. 10); 21 C.F.R. § 630.17(e). The regulations were transferred from Title 42 to Title 21 when the regulatory responsibilities previously assigned to DBS were taken over by the Bureau of Biologics. This transfer occurred after the product licenses were issued, but before the vaccine lot was released.

[Continued]

shall be released unless it is demonstrated to meet regulatory neurovirulence standards.[16] The agency is empowered to require samples from the manufacturer and to conduct its own evaluation of neurovirulence prior to the vaccine's distribution. When the agency takes action under this section, the vaccine cannot be released unless the agency issues a lot release approval.[17] The data submitted by the manufacturer on the vaccine lot containing Kevan's dose demonstrated excessive neurovirulence. The agency conducted its own review and confirmed that the vaccine exceeded the regulatory standards. Knowing that the vaccine was excessively neurovirulent, an agency employee nonetheless issued a lot release approval permitting the vaccine to be distributed to members of the public, among them Kevan Berkovitz. (J.A. 13).

The vaccine paralyzed Kevan in all of his limbs and caused a scoliosis, or curvature, of his spine. He is able to breathe only with the assistance of a respirator. His injuries are permanent.

In response to Petitioner's complaint setting forth these allegations, the United States filed a motion to dismiss, alleging that the challenged conduct was a discretionary function. The district court denied the government's motion, holding that violation of non-discriminatory regulations by agency employees is not protected conduct under section 2680(a) of the Federal Tort Claims Act.[18] A divided panel of the court of appeals

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[15] [Continued]

References regarding the lot release approval will therefore be to Title 21, C.F.R.

[16] 21 C.F.R. § 630.17(b).

[17] 21 C.F.R. § 610.2(a) (S.A. 10).

[18] The district court granted the motion to dismiss with respect to the claims at ¶ 20 of Petitioners' complaint (J.A. 14), alleging that the government was negligent in failing to order withdrawal of defective vaccine lots after release and in failing to require the

reversed. The majority held that implementation of the statute and regulations by agency employees was an immunized "discretionary function" under section 2680(a), because neither the statute nor the regulations were found to impose any affirmative mandatory obligations on the agency. Judge Higginbotham dissented. He found that the statute created a duty to receive the showing of regulatory compliance and, further, created a duty not to license when the manufacturer "has shown the government that its vaccine is defective". (Pet. App. 25a). Agency employees who issued the contested licenses and lot release approval here were acting in violation of "the clear command of federal law". (Pet. App. 24a) Immunity for such conduct is not preserved under section 2680(a).

SUMMARY OF ARGUMENT

Section 2680(a) of the Federal Tort Claims Act preserves immunity for the policy and decisionmaking functions of the Executive. This section does not immunize conduct undertaken in execution of a statute, regulation or administrative plan unless: (i) it is performed with due care, or in accordance with official directives; or (ii) the conduct comprises a discretionary function, involving the authorized exercise of policy judgment. *Dalehite v. United States*, 346 U.S. 15 (1953); *Varig Airlines*, 467 U.S. 797 (1984). The conduct here was admittedly negligent and in violation of regulations which do not authorize the exercise of policy judgment. Immunity is not preserved for such conduct under section 2680(a).

Neither the enabling statute nor the regulations in this case confer discretion on agency employees regarding implementation of the licensing plan. The statute authorizes the regulating agency to issue licenses *only* upon

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manufacturer to provide more specific warnings to health care providers. Petitioners did not seek review of the dismissal of these claims, and they are not part of the case presented here. The government's motion was denied with respect to all remaining claims.

a showing that the vaccine *meets* regulatory standards. If Congress' condition precedent—demonstrated compliance with all applicable regulations—is not met, the agency has no authority to issue the license. Conduct of agency employees which goes beyond the scope of the agency's statutory authority cannot be immunized as discretionary function. *Hatahley v. United States*, 351 U.S. 173 (1956).

The regulations here are similarly non-discretionary. The precise scope of compliance review is defined in objective terms; the standards to be met are objective standards; and the regulations mandate that all regulatory criteria be complied with before the license may issue. There is no room in these regulations for an agency employee's subjective judgment of the best—or more expedient—course. Violation of non-discretionary agency regulations is not a protected function under section 2680(a).

A finding of liability in this case would be fully consistent with the policy and broad remedial objectives of the Federal Tort Claims Act. It cannot intrude on the prerogatives of the policy-maker to insist that his directives be obeyed by subordinates. Therefore, no policy justification exists for excepting this child from the Act's basic objective of providing compensation for those who are injured by the negligence of government employees.

The policy underlying the Public Health Service Act must also be considered. Congress acted wisely in imposing such stringent regulation of live-virus products, which if defective, present a risk of epidemic harm to the public health. The government employees who administer the statute and its following regulations must be made to conform to the judgment of the policy-makers regarding the non-discretionary criteria which qualify such products for licensing. The decision below set agency employees free to decide for themselves what live-virus products may be distributed to the public. That was *not* Congress' intent. The decision below should be reversed.

ARGUMENT

I. Section 2680(a) Of The Federal Tort Claims Act Does Not Preserve Immunity For Negligent Conduct By Government Employees Which Violates Non-Discretionary Statutory And Regulatory Directives.

The defense of sovereign immunity asserted by the United States has its origin in the royal prerogative claimed by medieval English monarchs.[19] The doctrine was grafted onto the common law of the United States and operated to insulate the government from liability for any claim of damage caused by the conduct of its agents and employees. Recognizing the anomaly presented by a broad assertion of royal prerogative in a constitutional democracy,[20] and seeking to correct the injustice and hardship which result when government is not held accountable for injuries inflicted by its employees, Congress passed the Federal Tort Claims Act in 1946. The Act provides that the federal government shall be liable in tort "in the same manner and to the same extent as a private individual under like circumstances." 28 U.S.C. § 2674 (S.A. 1).[21] Congress intended this language to embody a sweeping waiver of immunity, *United States v. Yellow Cab Co.*, 340 U.S. 543, 547 (1951), in order to achieve the just purpose of compensating vic-

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[19] Blackstone defined royal prerogative as:

> that special preeminence which the King hath over and above all persons, and out of the course of the common law, in right of his royal dignity . . . [The King] owes no kind of subjection to any other potentate on earth.

I Commentaries 239, 241-242.

[20] *See, Owen v. City of Independence*, 445 U.S. 622, 645, n.28 (1980) ("it has never been understood how the doctrine of sovereign immunity came to be adopted in the American democracy").

[21] Liability is to be determined "in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b) (S.A. 1).

tims of governmental misfeasance. *Indian Towing Co. v. United States*, 350 U.S. 61, 68-69 (1955). This Court has repeatedly held that the Act must be read broadly in conformity with its remedial objectives. *Brooks v. United States*, 337 U.S. 49, 51 (1949); *Block v. Neal*, 460 U.S. 289, 298 (1983); *United States v. Muniz*, 374 U.S. 150, 165-166 (1963); *Rayonier v. United States*, 352 U.S. 315, 320 (1957); and *United States v. Aetna Casualty & Surety Co.*, 338 U.S. 366, 383 (1949).

Exceptions to the Act's broad waiver of immunity—set forth in 28 U.S.C. section 2680—must be construed narrowly to cover "only those circumstances which are within the words and reason" of the statutory language. *Dalehite v. United States*, 346 U.S. 15, 31 (1953). The Court is not free to enlarge the exceptions, *United States v. Yellow Cab*, 340 U.S. 543, 548 (1951), or to create exceptions beyond those expressly provided by Congress. *Rayonier v. United States*, 352 U.S. 315, 320 (1957).

At issue in the present case is the scope of the exception set forth in section 2680(a), which preserves immunity for:

> (a) Any claim based upon an act or omission of an employee of the Government *exercising due care, in the execution of a statute or regulation*, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a *discretionary function* or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

(Emphasis added.) Thus, under section 2680(a), acts of a government employee performed in execution of a statute or regulation are protected if, and only if, the employee exercised due care. Because the conduct of government employees in this case admittedly was not undertaken with the requisite "due care", the challenged

conduct is immune only if that conduct is a "discretionary function" within the meaning of section 2680(a).[22]

The legislative history of section 2680(a) demonstrates that the "discretionary function" exception is intended to preserve immunity for "the discretion of the executive or the administrator to act according to one's judgment of the best course", including "determinations made by administrators in establishing plans, specifications or schedules of operations." *Dalehite v. United States*, 346 U.S. 15, 34 (1953) (reviewing legislative history). As this Court made clear in *Dalehite*, "discretionary function" immunity primarily shields official policy making. *Id.* at 36 ("where there is room for policy judgment and decision there is discretion"). This immunity has limited application to governmental conduct that merely implements policy choices. Implementing conduct is protected only if a government employee (i) acts to further a discretionary policy choice *in accordance with official directions*, *id.* at 36; or (ii) is empowered to exercise discretion in the implementation of a policy choice. *Id.* at 33.[23]

Acts by government employees that violate mandatory statutory or regulatory directives are not immune from liability under the Act. *Hatahley v. United States*, 351 U.S. 173 (1956). At issue in *Hatahley* were actions of employees of the Department of the Interior impounding

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[22] A prior legislative proposal, S. 2221, 77th Cong., 2d Sess. (1942), set out the two clauses of section 2680(a) in two subsections. The final legislation incorporated them into the same paragraph, indicating a legislative intent that they be read together.

[23] The legislative history indicates Congress' intent to incorporate the principles of pre-existing common law in section 2680(a). *Dalehite*, *supra*, 346 U.S. at 27. *Dalehite*'s analysis is consistent with common law. *See, e.g., Marbury v. Madison*, 1 Cranch 137, 170 (1803), (separate "political" powers of the Executive protected); *Johnson v. District of Columbia*, 118 U.S. 19, 21 (1886) (conduct requiring implementation "according to the general plan so adopted" was not within the ambit of protected discretion, that only exercise of judgment being that needed to determine that the requisites of the plan had been met.).

115 allegedly "abandoned" horses found grazing on public land. The Federal Range Code, issued under the authority of the Taylor Grazing Act, authorized such impoundment only if government employees provided the owners with prior written notice and an order to remove the livestock from public lands. The Code also provided an express definition of "abandoned" livestock.

The Court held that the notice provisions of the Code were express conditions precedent to the exercise of power under the local impoundment law, and further, that the statutory definition of "abandoned" livestock had not been met. Because the terms and conditions of the Code were not complied with, the agents were found to have acted wrongfully and without statutory authority. The first clause of section 2680(a) offered no protection for such conduct, since the agents had not exercised due care in executing the statute and regulations. Under the second clause, the Court made clear that government employees who act in violation of the terms and conditions of the law, and therefore *beyond* the law, are not entitled to "discretionary function" immunity. *Id.* at 752.

The Federal Courts of Appeals have uniformly refused to find "discretionary function" immunity for conduct of government employees that violates mandatory statutory or regulatory directives. *See, e.g., United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 8 (3d Cir. Jan. 15 1988) ("conduct cannot be discretionary if it violates the Constitution, a statute, or an applicable regulation"); *Red Lake Band of Chippewa Indians v. United States*, 800 F.2d 1187, 1196 (D.C. Cir. 1986) ("government official has no discretion to violate the binding laws, regulations or policies that define the extent of his official powers"); *Collins v. United States*, 783 F.2d 1225, 1230 (5th Cir. 1986) (failure to follow a non-discretionary regulation "represented disobedience of official directions, simple and unadorned"); *C.P. Chemical Co. v. United States*, 810 F.2d 34, 39 (2d Cir. 1987) ("this is not a case where an agency ignored its own regulations or the clear mandate

of statutory procedure"); *Aslakson v. United States*, 790 F.2d 688, 693 (8th Cir. 1986) (failure to adhere to established agency policies not protected); *Birnbaum v. United States*, 588 F.2d 319, 329 (2d Cir. 1978) ("a discretionary function can only be one within the scope of authority . . . as delegated by statute or regulations"); *Andrews v. Benson*, 809 F.2d 1537, 1542 (11th Cir. 1987) (for purpose of determining official immunity, violation of safety regulations is not discretionary activity); *Jayvee Brand, Inc. v. United States*, 721 F.2d 385, 389 (D.C. Cir. 1983) ("It is clear that the exception does not apply when a government employee fails to follow obligatory procedures in applying a rule that is itself an exercise of discretion.").[24]

II. Both The Statute And Regulations Here Impose Non-Discretionary Conditions Precedent To The Exercise Of Licensing Authority Regarding Live-Virus Vaccines. Agency Employees Who Issued Product Licenses In Violation Of Those Conditions Were Not Performing An Immunized Discetionary Function.

The question whether a government employee is performing a "discretionary function" immunized by section 2680(a) requires a careful, two-step analysis.

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[24] The common law cases are in accord. *See, American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902) (conduct which is "unauthorized by the statute under which [a government employee] assumes to act" is not protected); *Spalding v. Vilas*, 161 U.S. 483, 498 (1896) (department head "keeping within his authority" is protected); *Kendall v. United States*, 12 Peters 524, 610, 626 (1838) (where Congress imposes duty on Executive, "the duty and responsibility grow out of and are subject to the control of the law").

See, also, Heckler v. Chaney, —— U.S. ——, 105 S.Ct. 1649, 1657 (1985), (in protecting discretionary activity from judicial review under the Administrative Procedure Act, "Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers"). *Also, see*, Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. Chi. L. R. 1300 (Fall 1987).

First, it must be determined whether Congress conferred discretion upon the agency to make policy judgments regarding how best to effectuate the intent of Congress, as expressed in the underlying the grant of authority. This is entirely a question of congressional intent, which depends on the particular enabling statute and will vary depending on the terms of that statute. If a government official seeks to make a policy choice that is *not* authorized by the enabling statute, the policy choice cannot qualify as a "discretionary function".[25]

Second, even if the statutory grant of authority confers some discretion upon the agency to determine the appropriate means to effectuate congressional intent, it must be determined whether or not the agency has established implementing regulations that confer discretion upon agency employees in the execution of the agency's policy choices. Within the bounds of its statutory authority, an agency may promulgate regulations that confer, or withhold, the power to exercise discretion in executing the intent of Congress. If agency regulations impose mandatory directives upon agency employees, an employee's decision to act in violation of the mandatory directives cannot qualify as "discretionary function".

The decisions of employees of the Division of Biologic Standards to license non-complying live poliovirus products cannot come within the "discretionary function" exception. Congress gave DBS no discretionary authority to issue a license when compliance with applicable safety regulations was not demonstrated. The regulations promulgated by the agency gave agency employees no discretionary authority in determining whether compliance was demonstrated.

By statute, DBS was empowered by Congress to issue licenses permitting the private manufacture of biologic

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[25] *See, Hatahley v. United States*, 351 U.S. 173 (1956) and cases cited, *supra*, at 13 and n.21.

products *only* upon a *showing* that the product for which a license is sought *meets* regulatory standards designed to insure its safety. 42 U.S.C. § 262(d) (S.A. —). Demonstrated compliance with *all* regulatory standards is a non-discretionary condition precedent to the exercise of power under this statute. No exceptions are provided; the grant of power is thus strictly limited. The government employee who issued the product licenses for the original virus strain and for the production seed admittedly did not comply with the express condition of the statute. Such conduct, which exceeded the agency's statutory authority, is not an immunized "discretionary function" under section 2680(a).

The regulations promulgated by the agency gave agency employees no authority to exercise policy judgment in determining whether the conditions of licensing were met. In the section titled, "Product licenses; issuance and conditions," the regulations reiterate that a license shall be issued "*only* upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations."[26] Compliance with regulatory standards is determined by evaluation of precise and objective criteria. No policy judgment is needed, for example, to determine whether two paralyzed Macaca monkeys is a greater number than none; whether three lesions are more than two; whether a lesion which advanced 2 cm beyond the point of inoculation has a greater spread than one which advanced .5 cm from the inoculation site.[27] Nor is policy judgment needed to determine whether at least 16 of 20 suckling mice less than 24 hours old survived for 14 days after intracerebral injection of .01 ml and intraperitoneal injection of .10 ml of the monovalent pool.[28] There is no room here for

[26] 42 C.F.R. § 73.5(a) (S.A. 4).

[27] 42 C.F.R. § 73.114(b)(1)(iii) (S.A. 7).

[28] 42 C.F.R. § 73.114(a)(3).

discretion, for a licensing decision based on an administrator's subjective judgment of the best course.[29]

In promulgating the regulations, the Surgeon General expressly *rejected* proposals that the regulations provide for flexibility in determining regulatory compliance. For example, it was suggested that the neurovirulence criteria require that the lot not *significantly* exceed the reference; that is not exceed *the range established for* the reference; that it is acceptable if the lot is *in the same range* as the reference.[30] The last of these proposals was made by Dr. Albert Sabin, who produced the original attenuated strain. The Surgeon General rejected Dr. Sabin's proposal, along with the others.

Aside from the majority below, every federal court which has considered this statutory and regulatory scheme has found it to impose mandatory obligations on the regulating agency.

Baker v. United States, 817 F.2d 560 (9th Cir. 1987), *petition for cert. filed*, 56 U.S.L.W. 3539 (U.S. Jan. 13, 1988) (No. 87-1180) involved a claim that an original poliovirus strain had been licensed in violation of the statute. In *Baker* data demonstrating the successful performance of all required tests had not been submitted with the licensing application. The government claimed

[29] Even the panel majority below agreed that conduct which can be measured by a readily ascertainable standard is not discretionary activity. (Pet. App. 14a). *See, also, Alabama Electric Cooperative, Inc. v. United States*, 769 F.2d 1523 (11th Cir. 1985); *Barton v. United States*, 609 F.2d 977, 979 (10th Cir. 1979). Also, *see, Westfall v. Erwin*, —— U.S. ——, 56 U.S.L.W. 4087, 4089 (1988) (discretion is more than "a modicum of choice"). At common law, *see, Roberts v. United States*, 176 U.S. 221, 231 (1899) (that a public officer was required to construe a statute in order to ascertain his duty under it did not render the duty discretionary); *Johnson v. District of Columbia*, 118 U.S. 19, 21 (1986), *supra*, n.23.

[30] *Griffin v. United States*, 351 F. Supp. 10, 26 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (3d Cir. 1974).

that the licensing was a discretionary function under section 2680(a). The court of appeals reviewed the statute and the regulations, concluding that:

> In this case the Secretary may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted . . . Agency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data. As to that there is no discretion.

Id. at 566.

In *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), plaintiffs contended that an original poliovirus strain had been licensed in violation of the statute and regulations. The court of appeals similarly rejected the government's claim that the conduct was protected discretionary function, holding that:

> The Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public.

Id. at 1273.

In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974)[31], which involved a lot release approval under the regulations, the court characterized the requirements of the regulations as "strict" and held that "no discretion was conferred to disregard the mandatory regulatory command." *Id.* at 1068. The court concluded that, "Although Congress has provided that activity within the authority of a Government official, if a 'discretionary function', may not be the basis of Government liability even if negligent or an abuse of discretion, Con-

[31] *Griffin* was overruled by the decision of the panel majority below. Prior to that decision, *Griffin* had been relied on or cited with approval in more than 80 cases covering every federal circuit in the country.

gress has not immunized such activity if it exceeds the authority conferred." *Id.* at 1069.[32]

The conclusion reached by these courts is the only logical construction of the statutory and regulatory language. Congress unquestionably has the power to impose mandatory executory obligations on an agency of its creation, thereby limiting the agency's power. The statute duly enacted by Congress clearly imposes such restrictions on agency authority here: *Licenses may be issued only upon a showing that the product meets regulatory standards designed to insure its safety.* The regulations promulgated to carry this statute into effect are equally restrictive. Neither confers discretionary authority to license a non-complying live-virus vaccine.

A. *Failure To Revoke The License Of Production Seed 45-B-85 After A Demonstrated Change In Neurovirulence Is Actionable Conduct.*

After production seed 45-B-85 was licensed, it demonstrated a change in neurovirulence, triggering the requirement that its license be revoked.[33] No action was taken, however, and the seed subsequently produced the vaccine monopool that paralyzed Kevan Berkovitz. Although what is at issue here is a failure to undertake

[32] *See, also, Schinder v. United States*, 661 F.2d 552 (6th Cir. 1981) reversing the lower court's dismissal of a vaccine licensing complaint. *Schindler*, however, did not pass on the mandatory or non-mandatory character of the regulations, remanding instead for development of a factual record. At trial the action was dismissed for failure of proof regarding regulatory non-compliance.

[33] The panel majority below did not distinguish among the four separate allegations of misconduct presented in the complaint. Each allegation rests on the same fundamental proposition: that there is no discretion to violate mandatory regulations. However, insofar as the revocation and lot release approval issues do not involve an explicit statutory directive, and depend on regulations distinct from those governing the licensing claims, the analysis is not identical.

affirmative conduct, the analysis is consistent with that in the preceding section.

The enabling statute makes explicit reference to regulation of the *continued* safety of the vaccine. 42 U.S.C. § 262(d). Given the ability of live viruses to change and return to morbid neurovirulence, the emphasis on continued safety is critical to the regulatory scheme. The regulations provide that whenever "the product for which the license has been issued, fails to conform to the standards in the regulations", the Surgeon General shall recommend revocation of the product license.[34] Once revoked, the license can only be reinstated upon a showing of compliance with regulatory standards.[35]

It is admitted that data submitted to the agency demonstrated that 45-B-85 had not been able to maintain the neurovirulence properties prescribed in the regulations and that failure to revoke its product license violated agency regulations. Such conduct is actionable under the construction and authorities set forth in the preceding Argument.[36]

B. *Issuance Of A Lot Release Approval For A Vaccine Lot Which Was Known To Be Excessively Neurovirulent Is Actionable Conduct.*

Consumer level vaccine lots do not require a product license. However, the manufacturer is required to test each vaccine lot for compliance with prescribed neurovirulence criteria[37] and to submit the test results to the

[34] 42 C.F.R. section 73.9 (S.A. 5).

[35] 42 C.F.R. section 73.15(a) (S.A. 5).

[36] It should be noted that Petitioners' Complaint does not refer to revocation of license, but rather to enforcement of the requalification requirement of § 73.110(b)(5) (S.A. 7). Particularly for the purposes of a motion to dismiss (*see*, n.2, *supra*), the complaint fairly encompasses the revocation issue.

[37] 21 C.F.R. §§ 610.1, 630.16 (S.A. 10). *See* n.15 *supra* regarding transfer of the regulations from Title 42, C.F.R., to Title 21, C.F.R.

agency,[38] which is empowered to intervene before the vaccine is distributed in order to confirm compliance with neurovirulence standards.[39] A strong argument can be made that the duty to confirm compliance is mandatory when the manufacturer's data demonstrates excessive neurovirulence, as it did here.[40] However, even if the *decision* to test were found to be discretionary, the implementing conduct is not. This section has been interpreted in *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982) as authorizing the issuance of the lot release approval only upon a showing of compliance with the neurovirulence criteria. Once the agency takes action under this section, its duties are the same as those which govern the issuance of product licenses: to review data and issue the lot release approval only upon a showing of regulatory compliance.[41]

It is admitted that the issuance of the lot release approval violated agency regulations. Under the preceding discussion, such conduct cannot be immunized as discretionary function.

[38] 21 C.F.R. § 630.17(e).

[39] 21 C.F.R. § 610.2 (S.A. 10).

[40] The regulations must be interpreted in light of the statutory directive that they be designed to insure the continued safety of the vaccine. It would be wholly inconsistent with the duties imposed on the agency by the overall statutory and regulatory scheme to contend that the agency was *not* required to act under this section when it had knowledge that a vaccine lot was dangerously neurovirulent. Further, Petitioners will prove at trial that the agency interpreted the regulation as mandatory when excessive neurovirulence was demonstrated.

[41] Testimony in *Griffin v. United States*, 351 F. Supp. 10 (1972), *aff'd*, 500 F.2d 1059 (1974), indicated that this was the agency's own interpretation of the regulation.

C. *The Panel Majority Below Misconstrued The Scope Of Section 2680(a).*

The agency employees whose conduct is in question here admittedly failed to use due care in executing the statute and regulations; were not empowered to make policy judgments; and were not acting in accordance with official directives. To the contrary, their conduct violated the directives of both Congress and the Surgeon General. Immunity is not preserved for such conduct under section 2680(a).

The majority below made three significant errors in analyzing this conduct. First was the contention that "Berkovitz can point to no regulation requiring the FDA to do anything. In other words, no regulation imposes a non-discretionary duty." (Pet.App. 17a-18a). This analysis misses the central contention of the lawsuit—that the agency *did* do something that it lacked the power to do. The duty *not* to act, where the conditions precedent to the lawful exercise of power are not met, is no less imperative than a requirement to undertake affirmative conduct.[42]

Second, the majority created an unprecedented category of protected conduct in holding that "non-discretionary operational level acts and omissions taken in furtherance of planning level discretionary decisions" are protected. (Pet.App. 16a). The majority's reliance on *Dalehite* for this proposition is wholly unfounded, since the majority omits *Dalehite*'s critical requirement that such conduct be *in accordance with official directions.*

[42] In Judge Higginbotham's analysis, the existence of the condition precedent to licensing creates an affirmative duty to receive the required showing of regulatory compliance. (Pet. App. 25i). This was also the approach of the court in *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987), construing the same statute.

Following *Dalehite*, in *Indian Towing v. United States*, 350 U.S. 61 (1955), the Court held that although the Coast Guard's decision to undertake operation of a lighthouse was an act of discretion, the Coast Guard was nonetheless liable under the Act for negligent execution of that policy in failing to keep the light in working order.[43] *See also, Block v. Neal*, 460 U.S. 289, 293 (1983); *Rayonier, Inc. v. United States*, 352 U.S. 315 (1957); *Eastern Airlines v. Union Trust Co.*, 221 F.2d 62, 74 (D.C. Cir.), *aff'd sub nom., United States v. Union Trust Co.*, 350 U.S. 907 (1955).

Further, the legislative history indicates that the one example on which there was consensus regarding Congress' consent to suit is that of the much-maligned government truck driver. If a government truck carrying ammonium nitrate fertilizer to the dock for loading ran a red light and crashed, causing an explosion, the government would be liable. Although the driver was furthering a discretionary plan, his conduct is "sufficiently separable" from policy-making conduct to be actionable.[44] The majority's construct, which would protect all implementing conduct, is plainly at odds with the statutory language, the legislative history and all prior precedent.

Finally, the majority's erroneous result was based in large part on a misunderstanding of this Court's decision in *Varig Airlines*. Properly understood, *Varig* compels a finding that the conduct at issue in the present case is

[43] In *Indian Towing* the government conceded that the discretionary function exception did not apply to such implementing conduct and instead argued that operation of a lighthouse was a "governmental function" which was entitled to *per se* protection under the Act. The Court found this definition of protected conduct to be "so finespun and capricious as to be almost incapable of being held in the mind for adequate formulation" and refused to endorse it. *Id.* at 68.

[44] *Gray v. Bell*, 712 F.2d 490, 515 (D.C. Cir. 1983).

not within the immunity preserved for "discretionary function".

III. *Varig Airlines* Protected The Policy-Making Function Of The FAA And The Implementation Of Policy In Accordance With Agency Directives. *Varig* Does Not Hold That Conduct Which Violates Non-Discretionary Directives Of Congress And Duly Promulgated Regulations Is Likewise Protected.

In *United States v. S.A. Empresa Aerea De Viacao Rio Grandense*, 467 U.S. 797 (1984), hereafter *Varig Airlines*, the Court expressly reaffirmed the reasoning of *Dalehite*.

The decision-making process was itself directly challenged in *Varig* by the allegation that the FAA's choice of a spot-inspection plan was negligent. Since the FAA was given express discretionary power to decide how, whether and when to inspect,[45] immunity was necessary to protect the agency's decision-making prerogatives. Insofar as the challenged conduct of FAA inspectors was performed in accordance with the plan, it was also protected. *Id.* at 814. As the Court again noted, what is protected by section 2680(a) is "legislative and administrative decisions grounded in social, economic, and political policy." *Id.*

That is not the case presented here. The Surgeon General's *plan* is not being challenged, and the only conduct complained of is conduct which was distinctly *not* in accordance with his official directives. The integrity of the agency's decision-making process is in no way jeopardized by these allegations.

Further, in *Varig* the FAA's statutory power to certify aircraft was unrestricted. The Administrator was

[45] 49 U.S.C. § 1421(a)(3)(C) authorized the Administrator to prescribe reasonable regulations governing inspection of aircraft and "in the discretion of the Administrator, the period for, and the manner in which, such inspection . . . shall be made."

given express power to issue certificates *whether or not* the plane met regulatory standards.[46] The ultimate act complained of in *Varig*—issuance of a type certificate for a non-complying plane—was within the scope of the agency's statutory authority.

Agency power here was restricted by a mandatory condition precedent to the exercise of licensing power. DBS was empowered to issue a license for biologic products *only* upon a showing of regulatory compliance. No exemptions were authorized. The ultimate act complained of—issuance of a license for a virus strain and seed that did *not* comply with regulatory standards—was beyond the agency's statutory authority.

In addition, discretion was conferred by the *regulations* in *Varig*, which specifically empowered subordinate employees to make policy judgments in implementing the inspection plan. *Id.* at 820. Thus, the inspectors' conduct is protected, even if negligent.[47]

In the present case, the regulations did not give agency employees discretion to make policy judgments in deter-

[46] 49 U.S.C. § 1421(c) authorizes the Administrator to "grant exemption from the requirements of any rule or regulation . . . if [he] finds that such action would be in the public interest."

[47] Because *Varig* considered a failure to inspect, the question nominally left unanswered was whether an actual negligent inspection by the FAA would be protected. Since negligence is irrelevant where operational employees are authorized to exercise discretion, the conduct would be protected. It should be noted that although *Varig* did not directly address *Dalehite's* dichotomy between planning and implementing conduct, the Court's emphasis on "the nature of the conduct" as one of the principal determinants of discretionary function has been analogously read in the lower courts. *See, e.g., United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 10-11 (3d Cir. Jan. 15, 1988); *Chotin v. United States*, 819 F.2d 1342, 1347 (6th Cir. 1987) (en banc); *Drake Towing Company v. Meisner Marine Construction Company*, 765 F.2d 1060, 1065 (11th Cir. 1985).

mining regulatory compliance. The regulations defined precisely the scope of the compliance review and directed that review of the licensing application in accordance with the regulations be undertaken in *every* case.

The panel majority below disregarded these distinctions, relying instead on the broad statement that, "It would be incongruous to conclude that Congress intended the FAA to exercise a lesser supervision over the safety of aircraft than the FDA was to exercise over the safety of polio vaccine." (Pet. App. 20a)

There are two problems with this statement. First, it elevates the court's policy view on the advisability of congruity in federal regulation above the expressed judgment of Congress. The plain language of the empowering statutes demonstrates the differences in the two schemes Congress devised.

Addressing the statement on its merits, the decision to create a more stringent scheme regarding biologic products is not "incongruous." Relevant factors to be considered in devising a regulatory scheme would presumably include the feasibility of comprehensive government regulation, the magnitude of risk presented by unregulated private activity, and the public interest to be advanced by government involvement.

It would not be feasible for the FAA to meet a mandatory obligation to inspect every plane and confirm compliance with every regulation. A Boeing 707 cannot readily be delivered to an FAA lab for compliance review. Not only the size of the "product" to be regulated, but also the number of aircraft, the number of discrete component parts in each plane, the number of manufacturers and the volume of applicable regulations (covering over 500 pages in Title 14 of the Code), would make a mandatory system unworkable.[48] And so Congress charged the FAA only with the duty of "promoting" air safety by "monitoring" compliance, in whatever way the agency deemed appropriate.

It *is*, however, feasible for the agency regulating biologic products to meet mandatory obligations. There is no problem with size: all of the poliovirus vaccine produced since 1963 would fit into the overhead compartments of one Boeing 707. The regulations, which cover only 9 pages in the Code, are objective and precise; determining compliance requires only that an agency employee review the data delivered to his or her office and numerically match the test results against the Reference strain. If adequate data are not submitted, or if the data demonstrate excessive neurovirulence or other regulatory non-compliance, the only action required of the employee is to reject the application.

The comparative risk presented by the unregulated manufacture of live-virus products also justifies the more stringent regulatory scheme. The number of people put at risk by a defective plane is not insignificant. However, one vaccine monopool produces *one million* doses of live-virus vaccine, capable of producing contagious and morbid paralytic disease not only in recipients, but also in those with whom they come in contact.

Regarding public interest, there is an issue beyond the avoidance of risks to the public health. No one is *required* to board an airplane, nor does the federal government involve itself in persuading members of the public to travel by air. The federal government *does*, however, involve itself in promoting mass immunization programs.[49]

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[48] *See*, National Academy of Sciences, Committee on FAA Airworthiness Certification Procedures, *Improving Air Safety*, p. 29 (1980), discussing the volume of applications for type certificates.

[49] *See, e.g.*, 42 U.S.C. § 247b(j)(1); Staff of House Subcommittee on Health and The Environment, 99th Cong., 2d Sess., *Report on Childhood Immunizations* (Comm. Print 1986), pp. 50-55.

All fifty states and the District of Columbia *require* that children receive polio vaccine before they can be admitted to school.[50] The government makes affirmative efforts to persuade the public to participate in these programs, and the public responds, based in some measure on the assurance of involvement by a corporate body whose only concern, they believe, is not profit, but their collective well-being.

For all of these reasons, it was not "incongruous" for Congress to impose a non-discretionary condition precedent to licensing power, requiring this agency to be more than an occasional "monitor" of industry compliance.

Varig reviewed a statutory and regulatory plan shot through with discretion, and the implementing conduct demonstrated faithful execution of the plan. That is *not* the case presented here. *Varig* does not, therefore, support a finding of immunity.

IV. Section 2680(a) Does Not Provide *Per Se* Immunity For Regulatory Conduct.

Implicitly recognizing that the conduct at issue here does not involve discretionary function, the government argued to the court below that *all* regulatory conduct, including violation of mandatory regulations, enjoys *per se* immunity under section 2680(a). This proposition has been rejected by every federal court to which the government has presented it, including the panel majority below. (Pet. App. 12a-15a)[51] The reasons are sound.

First, there is nothing in the language of the statute which supports the argument. If Congress had intended

[50] *Id.* at Appendix B.

[51] *See, e.g., Collins v. United States*, 783 F.2d 1225, 1229 (5th Cir. 1986); *Baker v. United States*, 817 F.2d 560, 565 (9th Cir 1987); *United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 10 (3d Cir. Jan. 15, 1988); *Griffin v. United States*, 500 F.2d 1059, 1063-64 (3d Cir. 1974).

to protect all regulatory conduct, they could very easily have done so. A third clause could simply have been added to section 2680(a), providing that "all regulatory activities of federal agencies are exempt." However that was not done. The statute enacted by Congress provides that only *discretionary acts* of federal agencies, including regulatory agencies, are immune. The inapplicability of a *per se* approach to this section is indicated by the Court's observation that there are no bright line tests in this area, that the precise contours of the exception cannot be defined, and that analysis must proceed on a case by case basis. *Dalehite, supra*, 346 U.S. at 35; *Varig Airlines, supra*, 467 U.S. at 813. That a *per se* approach would contravene Congress' intent is further evidenced by the legislative history, indicating that "the common law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of non-regulatory agencies."[52]

The government has previously urged the Court to adopt a *per se* approach extending immunity to all "governmental functions". The Court has repeatedly rejected such a construction as not within the express terms of the statute.[53]

In *Varig*, the Court chose not to accept the government's invitation to extend *per se* immunity to regulatory conduct, engaging instead in a careful analysis of the extent of the FAA's lawful discretionary power. Even the broadest language in *Varig*—"Whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the government acting in its role as a regulator of the

[52] *Dalehite, supra*, 346 U.S. at 29, n.21.

[53] *Indian Towing Co. v. United States*, 350 U.S. 61, 68 (1955); *Rayonier v. United States*, 352 U.S. 315, 319 (1957); *United States v. Muniz*, 374 U.S. 150 (1963).

conduct of private individuals"—acknowledges that only the *discretionary acts* of regulators are protected. *Varig Airlines, supra*, 467 U.S. at 813-814. Further, *Varig* stressed that what is important in the analysis of discretionary function is the nature of the conduct, not the status of the actor. *Varig Airlines, supra*, 467 U.S. at 813. The actor's status as regulator, therefore, should not be relevant.

The cases refusing to adopt a *per se* approach are fully consistent with the Court's acknowledgment that it is not free to enlarge the exceptions to liability under the Act [54] or to read into the Act exceptions not expressly provided by Congress.[55]

Petitioners respectfully submit that the Court should put to rest, with its opinion in this case, the government's assertion of *per se* immunity for regulatory conduct.

V. The Policies Underlying Both The Federal Tort Claims Act And The Public Health Service Act Support A Finding Of Liability.

The principal justification for the exception to liability in section 2680(a) is "to prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic and political policy". *Varig Airlines, supra*, 467 U.S. at 814. An exception which prohibits *judicial* second-guessing of policy decisions cannot be read to protect agency subordinates engaged in that very conduct. The exception would swallow itself if extended to cover subordinate acts which flout the expressed policy of the Executive, thereby undermining the integrity of the decision-making process. Further, a holding that agency functionaries must adhere to the rules laid down by the policy-makers cannot be said to

[54] *United States v. Yellow Cab Co.*, 340 U.S. 543, 548 (1951).

[55] *Rayonier v. United States*, 352 U.S. 315, 320 (1957).

impair the agency's ability to function. To the contrary, on a policy level the position of the decision-maker is strengthened. On an operational level, holding employees engaged in non-discretionary conduct to a standard of due care can only improve the functioning of the agency.[56]

The avoidance of financial liability is an insufficient justification for extending immunity to the conduct here, particularly given the Act's fundamental objective to *provide* relief for people injured by negligent government employees. As this Court has held, it should not "as self-constituted guardian of the Treasury import immunity back into a statute designed to limit it." *Indian Towing Co. v. United States*, 350 U.S. 61, 69 (1955).

There is no policy justification for excepting Kevan Berkovitz from the Act's fundamental objective to provide compensation for those injured by the wrongdoing of government employees.[57]

The policy underlying the Public Health Service Act should also be considered. Congress purposefully imposed limitations on the agency's authority to license biologic products, including live-virus products capable of producing epidemic disease. The agency, acknowledging its obligation under the statute to promulgate regulations designed to insure the continued safety of such products, adopted stringent, non-discretionary licensing criteria.

[56] An extensive discussion of the policy justifications for section 2680(a), and their inapplicability to violation of mandatory regulations, is found in Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. Chi. L. Rev. 1300, 1327-1334 (Fall 1987).

[57] In November, 1986, Congress passed legislation to provide compensation, without proof of negligence, for injuries caused by certain vaccines, including polio vaccine. 42 U.S.C. § 300aa-1, *et seq.* For injuries occurring before the effective date of the Act, as Kevan's, compensation is limited to unreimbursed medical expenses incurred subsequent to a determination of entitlement. 42 U.S.C. § 300aa-15(b).

Subordinate employees of the regulating agency cannot be permitted to disregard those criteria and decide for themselves what biologic products may be distributed to the public. The judgment of Congress, and of the Surgeon General, must be adhered to.

CONCLUSION

The judgment of the court of appeals, remanding to the district court with instructions to dismiss Petitioners' action, should be reversed.

Respectfully submitted,

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STATUTORY APPENDIX

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28 U.S.C. § 1346. United States as defendant

* * * *

(b) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

* * * *

28 U.S.C. § 2674. Liability of United States

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.

If, however, in any case wherein death was caused, the law of the place where the act or omission complained of occurred provides, or has been construed to provide, for damages only punitive in nature, the United States shall be liable for actual or compensatory damages, measured by the pecuniary injuries resulting from such death to the persons respectively, for whose benefit the action was brought, in lieu thereof. June 25, 1948, c. 646, 62 Stat. 983.

28 U.S.C. § 2680. Exceptions

The provisions of this chapter and section 1346(b) of this title shall not apply to—

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

42 U.S.C. § 262. Regulation of biological products

* * * *

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

* * * *

Title 42, C.F.R. (1961)

LICENSES: PROCEDURE

§ 73.2. Two forms of licenses.

There shall be two forms of licenses: establishment and product.

§ 73.3 Application for establishment and product licenses; procedure for filing.

To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Division of Biologics Standards, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency, a full description of manufacturing methods, data establishing stability of the product through the dating period, sample(s) representative of the product to be sold, bartered or exchanged or offered, sent, carried or brought for sale, barter or exchange, summaries of results of tests performed on the lot(s) represented by the submitted sample(s), and specimens of the labels, enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data shall have been received from the manufacturer by the Division of Biologics Standards.

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§ 73.5 Product licenses: issuance and conditions.

(a) *Examination—compliance with standards.* A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this part: *Provided*, That no product license shall be issued except upon a determination that the establishment

complies with the establishment standards prescribed in the regulations contained in this part, applicable to the manufacture of such product.

• • • •

§ 73.9 Issuance, revocation or suspension.

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The Surgeon General shall recommend to the Secretary that a license be suspended or revoked whenever he finds, after notice and opportunity for hearing, that . . . (c) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the standards in the regulations in this part, as herein prescribed or as hereafter amended, designed to insure the continued safety, purity, and potency of the manufactured product.

• • • •

§ 73.15 Licenses: reissuance.

(a) *Compliance with standards.* An establishment or product license, previously suspended or revoked, whether upon application, or for failure to comply with standards or changes in standards prescribed in the regulations in this part, may be reissued or reinstated upon a showing of compliance with required standards and upon such inspection and examination as may be considered necessary by the Director of the Division of Biologics Standards.

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ADDITIONAL STANDARDS: POLIOVIRUS VACCINE, LIVE, ORAL

§ 73.110 The product.

(a) *Proper name and definition.* For the purpose of section 351(a)(2) of the Act and § 73.1(k), the proper name of this product shall be "Poliovirus Vaccine, Live, Oral", followed by a designation of the form in which the vaccine is distributed by the manufacturer. The vaccine shall be a preparation of one or more live, attenu-

ated poliovirus grown in monkey kidney cell cultures, prepared in a form suitable for oral administration.

(b) *Criteria for acceptable strains and acceptable seed virus.* (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including rct/40, d, MS.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless, (i) data are submitted to the Surgeon General which establish that each strain is free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 73.114(b), 73.115, and 73.117. Susceptibility shall be demonstrated by blood tests, stool examination and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents.

(4) No seed virus shall be used for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the NIH Reference Attenuated Poliovirus. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test prescribed in § 73.114(b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least ten monkeys shall be infected with a total of 5.0 ml. of the seed virus under test if one or

more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of ten monkeys using the NIH Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than $10^{7.7}$ $TCID_{50}$ of viral inoculum. All monkeys shall be observed for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus, as prescribed in § 73.114(b)(1)(iii).

(5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus and upon introduction of a new production seed lot and as often as necessary otherwise to establish to the satisfaction of the Surgeon General that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 73.114(b)(1).

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§ 73.114 Test for safety.

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(b) *Tests after filtration.* The following test relating to safety shall be performed after the filtration process, on each monovalent virus pool or on each multiple thereof (monovalent lot):

(1) *Neurovirulence in monkeys.* Each monovalent virus pool or monovalent lot shall be tested in comparison with the NIH Reference Attenuated Poliovirus for neurovirulence in Macaca monkeys by both the intrathalamic and intraspinal routes of injection. A preinjection serum sample obtained from each monkey must be shown to contain no neutralizing antibody in a dilution of 1:4 when tested against no more than 1,000 $TCID_{50}$ of each of the three types of poliovirus. The neurovirulence tests are not valid unless the sample contains at least $10^{7.0}$ $TCID_{50}$ per ml. when titrated in comparison with the

NIH Reference Poliovirus, Live, Attenuated of the appropriate type. All monkeys shall be observed for 17 to 21 days, under the supervision of a qualified pathologist, physician or veterinarian, and any evidence of physical abnormalities indicative of poliomyelitis or other viral infections shall be recorded.

(i) *Intrathalamic inoculation.* Each of at least ten Macaca monkeys shall be injected intrathalamically with 1.0 ml. of virus pool material containing at least $10^{7.0}$ $TCID_{50}$ per ml. and each of at least ten additional Macaca monkeys shall be injected intrathalamically with 1.0 ml of a 10^{-1} dilution thereof. Comparative evaluations shall be made with the virus pool under test and the NIH reference material. Only monkeys that show evidence of inoculation into the thalamus shall be considered as having been injected satisfactorily.

(ii) *Intraspinal inoculation.* Each of a group of at least five Macaca monkeys shall be injected intraspinally with 0.2 ml. of virus pool material containing at least $10^{7.0}$ $TCID_{50}$ per ml. and each monkey in four additional groups of at least five Macaca monkeys shall be injected intraspinally with 0.2 ml. of 10^{-1}, 10^{-2}, 10^{-3}, and 10^{-4} dilutions thereof, respectively. Comparative evaluations shall be made with the virus pool under test and the NIH reference material. Only monkeys that show microscopic evidence of inoculation into the gray matter of the lumbar cord shall be considered as having been injected satisfactorily.

(iii) *Determination of neurovirulence.* At the conclusion of the observation period comparative histopathological examinations shall be made of the lumbar cord, cervical cord, lower medulla, upper medulla and mesencaphalon of each monkey in the groups injected with virus under test and those injected with the NIH Reference Attenuated poliovirus, except that for animals dying during the test period, these examinations shall be made immediately after death. The animals shall be examined to ascertain whether the distribution and histological nature of the lesions are characteristic of poliovirus infection. A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine manufacture only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Poliovirus.

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Title 21 C.F.R. (1978)

Subpart A—Release Requirements

§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.

§ 610.2 Requests for samples and protocols; official release.

(a) *General.* Samples of any lot of any licensed product, except for radioactive biological products, together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Bureau of Biologics. Upon notification by the Director, Bureau of Biologics, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Bureau of Biologics: *Provided,* That the Director, Bureau of Biologics, shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

* * * *

(b) *Consistency of manufacture.* No lot of vaccine shall be released unless each monovalent pool contained therein is one of a series of five consecutive pools of the same type, each pool having been manufactured by the same procedures, and each having met the criteria of neurovirulence for monkeys prescribed in § 630.16(b)(1), and of in vitro markers prescribed in § 630.16(b)(3).